

Application No. 10/628,787  
Amdt. dated September 29, 2006  
Reply to Office action of June 29, 2006

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#### Remarks/Arguments

Claims 1-9 stand rejected. Claims 35-40 have been withdrawn by the Examiner. The claims stand rejected as follows:

Claims 1-8 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Number 6,596,304 (the '304 patent), which is said to disclose collagen I, III and fibroblasts.

Claim 9 is rejected under 35 U.S.C. § 103(a) as being obvious in light of the '304 patent in view of U.S. Patent Number 6,077,987 ('987 patent).

#### Restriction – Withdrawal of Claims 35-40.

Applicant respectively disagrees with the Action's statement that the new claims 35-40 are directed to a new invention. Claims 35-40 are directed to the same invention as the original claims, e.g., original claim 1. Claim 1 as originally filed relates to a collagenous material and at least one non-living cellular component. Similarly, the new claims 35-40 are directed to "an acellular collagenous material selected from collagen type I, interstitial collagens, collagen type III, V, IX and combinations thereof; and at least one non-living cellular component" and the original claims 1-35 as originally grouped relate to a "collagenous material; and at least one non-living cellular component." The new claims 35-40 and original claims 1-34 are clearly directed to the same invention. Applicant respectively requests entry and examination of claims 35-40 and rejoinder of claims 35-40 with claims 1-9.

#### Rejection under 35 U.S.C. §102(e).

Claims 1-8 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Number 6,596,304 (the '304 patent), which is said to disclose collagen I, III and fibroblasts. The '304 patent fails to anticipate the present invention under 35 U.S.C. § 102(e) because it does not include each and every element of the invention as amended. The '304 patent clearly fails as prior art because the collagen used is heat denatured, that is, it is not in its natural state. The '304 patent disclosure teaches to prepare the patch by heat denaturation of the collagen at 40 to 50 degrees centigrade, thereby eliminating its three-dimensional structure. As such, the collagen of the '304 patent is not the same as the acellular collagen claimed herein. The '304 patent does not provide an anti-adhesion patch having an acid-treated nondenatured acellular collagenous material and at least one non-living cellular component.

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Thus, it is clear that the '304 patent does not show each and every element of claims 1-8 as amended and Applicant, therefore, submits that the rejection of claims 1-8 under 35 U.S.C. §§ 102(e) over the art cited is improper and should be withdrawn.

**Rejections for Obviousness under 35 U.S.C. § 103(a)**

To sustain the present rejection of claim 9 under 35 U.S.C. § 103(a), a prima facie case of obviousness must be established. Applicants respectively submit that a prima facie case of obviousness has not been met as the Action does not teach or suggest all the claim limitations; there is not a reasonable expectation of success; and there is no suggestion or motivation to modify the references or to combine reference teachings. (see MPEP § 2142).

Claim 9 is rejected under 35 U.S.C. § 103(a) as being obvious in light of the '304 patent, in view of the '987 patent. The Applicant submits that the '304 patent in view of the '987 patents fail as prior art for failing to teach or suggest all the claim limitations for the same reasons stated in the response to the 35 U.S.C. §102(e)rejected, incorporated herein by reference.

Specifically, the '987 patent discloses cells that are implanted at a site in a patient and not used *in-vitro* to remodel collagen. Also, the cells are genetically engineered *in-vitro* to express bioactive molecules, e.g., bone growth factors, cartilage growth factors, nerve growth factors, and general growth factors important in wound healing and tissue repair in an amount effective to enhance the temporal sequence of wound repair, to alter the rate of cell proliferation, to increase the metabolic synthesis of extracellular matrix proteins, or to direct phenotypic expression in endogenous cell populations. Applicants also submit that there is no reasonable expectation of success and there is no suggestion or motivation to modify or combine the references. The process for the development of engineering a cell is complex and involves several intracellular and extracellular steps.

A prima facie case of obviousness has not been established. Neither the '304 patent nor the '987 patent show each and every element of claim 9, provide a suggestion or motivation to modify the reference, or provide a reasonable expectation of success. Therefore, Applicant submits that the rejection of claim 9 under 35 U.S.C. §§ 103(a) over the art cited should be withdrawn.

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**Conclusion**

In light of the remarks and arguments presented above, Applicant respectfully submits that the claims in the Application are in condition for allowance. Applicant respectfully requests rejoinder of claims 1-9 and 35-40. Favorable consideration and allowance of the pending claims is therefore respectfully requested.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: September 29, 2006

Respectfully submitted,



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